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By Charles H. Lively ^{Signature} October 17, 1986 ^{Date} 11-12-88 ¹¹⁻¹²⁻⁸⁸
 EL LILLY AND COMPANY
 PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David B. Anderson, et al.)
 Serial No.: 811,059)
 Filed : December 19, 1985) Group Art Unit: 125
 For : GROWTH PROMOTION) Examiner: F. Waddell
 Docket No.: X-5683B)

RESPONSE TO OFFICE ACTION

Commissioner of Patents and Trademarks
 Washington, D.C. 20231

Sir:

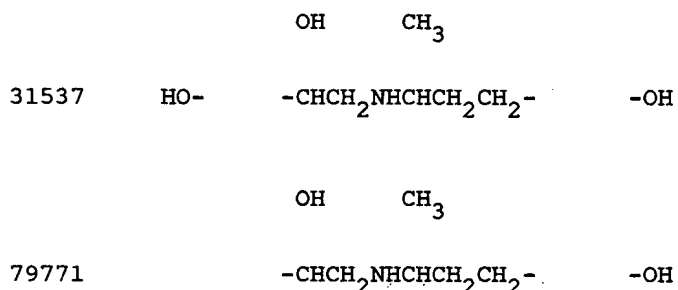
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 GROUP 120

This letter is in response to the Office Action dated June 17, 1986, Paper No. 5.

Applicants submit herewith copies of two Supplemental Information Disclosure Statements that were recently submitted in a related case, Serial No. 860,719, which is a continuation of the parent of the present case. The relevance of the cited art is set forth in the Information Disclosure Statements.

Claims 12, 23, 35, and 36 are in the present case. The claims are directed to a method of promoting growth in ruminant animals and to a method of improving leanness in domesticated animals in general. All claims stand rejected under 35 U.S.C. 103 as allegedly rendered obvious by Kiernam, EPA 26293, and Baker et al., EPA 49728, in view of Dijk et al. or Mills, EPA 7205. The Examiner asserts the primary references teach the growth promotion utility for structurally related phenethanolamines, and the secondary references teach the phenethanolamines now required to carry out the presently claimed method.

Applicants submitted in the parent application declaration evidence establishing an invention compound has unexpected biological activities when compared to a prior art compound. Specifically, Applicants demonstrated that the invention compound known as 31537 causes a greater increase in growth promotion and feed efficiency utilization in swine when compared to a compound (79771) described by Mills et al. in U.S. Patent No. 4,391,826. The compounds have the following structures:



Mills '826 teaches that 79771 is active as an anti-obesity agent and in improving leanness in domestic animals. The reference does not teach that β -phenethanolamines would be useful as growth promoters and the reference lacks any suggestion that the compound 31537 would have any unexpected biological properties relative to the Mills et al. 79771. Applicants submit herewith a Declaration by D. B. Anderson establishing that invention compound 31537 has unexpectedly greater growth promotion activity and feed efficiency activity in steers when compared directly with Mills et al. 79771. The Declaration establishes that 31537 caused a 28.2% increase in feed efficiency over untreated controls, whereas the Mills et al. compound 79771

caused only a 9.2% increase. The Declaration also establishes that the invention compound 31537 effected a 23.8% increase in average daily gain of the steers when compared to controls, while the Mills et al. compound 79771 caused only an 8.2% increase in average daily gain. In short, the Declaration by Anderson establishes that the invention compound 31537 is about three-fold more active as a growth promoter than the Mills et al. compound 79771 when administered to ruminants. Accordingly, the Declaration evidence is believed to establish the patentability of the invention recited in Claims 35, 36, and 12, which is limited to a method of promoting growth and a method of improving feed efficiency in ruminants such as steers.

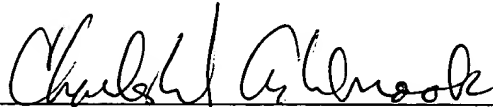
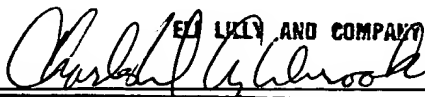
Claim 23 is a method for improving leanness in domesticated animals comprising administering a group of β -phenethanolamines, one of which is compound 31537. The accompanying Declaration by Dr. Jones establishes that one of the invention compounds, namely 31537, causes a substantially greater improvement in carcass leanness of swine than does the Mills et al. compound 79771. The Declaration by Dr. Jones presents the results of a long-term growth promotion study on finisher pigs and also establishes the amount of fat or leanness of the pigs following their slaughter.

The growth promotion data presented in the Declaration is completely consistent with that presented earlier in the parent case. The Declaration establishes that compound 31537 caused a 12% increase in average daily gain of the treated pigs compared to untreated controls, whereas the Mills et al. compound 79771 actually effected a reduction in average daily gain of 1.3%. Additionally, compound 31537 was shown to cause a 13.2%



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FEE AUTHORIZATION LETTER				GROUP 120 X-5683B		
SERIAL NO.	FILING DATE	EXAMINER		GROUP ART UNIT		
811,059	12/19/85	F. Waddell		125		
IN RE APPLICATION OF David B. Anderson et al. For: GROWTH PROMOTION						
TO THE COMMISSIONER OF PATENTS AND TRADEMARKS: <input checked="" type="checkbox"/> Applicant(s) petition(s) for an extension of time under 37 C.F.R. 1.136 to file the accompanying: <input checked="" type="checkbox"/> Response within one month of original due date (\$56.00) <input type="checkbox"/> Response within two months of original due date (\$170.00) <input type="checkbox"/> Response within three months of original due date (\$390.00) <input type="checkbox"/> Response within four months of original due date (\$610.00) <input type="checkbox"/> The accompanying papers include amended claims. The fee has been calculated as follows:						
CLAIMS AS AMENDED						
(1)	(2) CLAIMS REMAINING AFTER AMENDMENT	(3)	(4) HIGHEST NUMBER PREVIOUSLY PAID FOR	(5) NO. OF EXTRA CLAIMS PRESENT	(6) RATE	(7) ADDITIONAL FEE
TOTAL CLAIMS	*	MINUS	** =		× \$12	=
INDEP. CLAIMS	*	MINUS	*** =		× \$34	=
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT						
<p>*If the entry in column 2 is less than the entry in column 4, write "0" in column 5. **If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space. ***If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.</p> <p><input type="checkbox"/> The following other fees are incurred by the accompanying papers. <input type="checkbox"/> <input type="checkbox"/></p> <p>Please charge DEPOSIT ACCOUNT NO. 05-0830 in the amount of \$ <u>56.00</u></p> <p>Two copies of this sheet are enclosed.</p> <div style="text-align: right;"> Charles W. Ashbrook Attorney for Applicants Registration No. 27,610 Phone: 317-261-6015</div> <div style="text-align: left;">Eli Lilly and Company Patent Division/ CWA LILLY CORPORATE CENTER Indianapolis, Indiana 46285 <u>October 17, 1986</u></div> <div style="text-align: center;">CERTIFICATE OF MAILING <small>I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commission of Patents and Trademarks, Washington, D.C. 20231, on the date appearing below.</small>  By Eli Lilly and Company Signature <u>October 17, 1986</u> Date</div>						